

For the use only of a Registered Medical Practitioners or a Hospital or a Laboratory



Package leaflet: Information for the user Carboplatin 10 mg/ml Intravenous Infusion carboplatin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Carboplatin Intravenous Infusion is and what it is used for
2. What you need to know before you use Carboplatin Intravenous Infusion
3. How to use Carboplatin Intravenous Infusion
4. Possible side effects
5. How to store Carboplatin Intravenous Infusion
6. Contents of the pack and other information

1. What Carboplatin Intravenous Infusion is and what it is used for

Carboplatin Intravenous Infusion is an anti-cancer medicine. Treatment with an anti-cancer medicine is sometimes called cancer chemotherapy. Carboplatin is used in the treatment of some types of lung cancer and ovarian cancer.

2. What you need to know before you use Carboplatin Intravenous Infusion

Do not use Carboplatin Intravenous Infusion

- if you are allergic to carboplatin or to any of the ingredients of this medicine (listed in section 6)
- if you have had hypersensitivity to similar platinum containing medicines in the past
- if you have severe kidney disease
- if you have fewer blood cells than normal (your doctor will check this with a blood test)
- if you have a tumour that bleeds
- if you plan to receive a yellow fever vaccination or have just received one

Tell your doctor if any of the above applies to you before this medicine is used.

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before using Carboplatin Intravenous Infusion

- if you are pregnant or if there is a chance you may be pregnant.
- if you are breast-feeding.
- if you have mild renal disease. Your doctor will want to monitor you more regularly.
- if you are elderly (over 65 years old).
- if you have been treated with cisplatin or similar anti-cancer medicines in the past, carboplatin may cause abnormalities in your nervous system, such as pins and needles or hearing and vision problems. Your doctor may regularly assess you.

- if you have headache, altered mental functioning, seizures and abnormal vision (from blurriness to vision loss).
- if you develop extreme tiredness and shortness of breath with decreased number of red blood cells, (haemolytic anaemia), alone or combined with low platelet count, abnormal bruising (thrombocytopenia) and kidney disease where you pass little or no urine (symptoms of Haemolytic-uraemic syndrome).
- if you have fever (temperature greater than or equal to 38°C), or chills, which could be signs of infection. You may be at risk of getting an infection of the blood.

Other medicines and Carboplatin Intravenous Infusion

Tell your doctor, pharmacist or nurse if you taking, have recently taken or might take any other medicines, for example:

- medicines which can reduce the number of cells in your blood, at the same time as carboplatin, may require changes to the dosage and frequency of your carboplatin treatment
- some antibiotics called aminoglycosides, vancomycin or capreomycin, at the same time as carboplatin, may increase the risk of kidney or hearing problems
- some water tablets (diuretics), at the same time as carboplatin, may increase the risk of kidney or hearing problems
- live or live-attenuated vaccines (for yellow fever vaccine see section 2. Do not use Carboplatin Intravenous Infusion)
- blood thinning medicines e.g. warfarin, at the same time as carboplatin, may require an increase in frequency of blood coagulation monitoring
- phenytoin and fosphenytoin (used to treat various types of convulsions and seizures), at the same time as carboplatin, may increase the risk of a seizure
- other medicines which decrease the activity of the immune system (e.g. ciclosporin, tacrolimus, sirolimus)

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Due to the possible risk of birth defects, female

patients of childbearing potential should take contraceptive measures before and during treatment with carboplatin.

Men treated with this medicine are advised not to father a child during, and up to 6 months after treatment. Advice on conservation of sperm should be sought prior to treatment because of the possibility of irreversible infertility.

Treatment with carboplatin may temporarily or permanently reduce fertility in men and women. Tell your doctor if you have concerns.

Driving and using machines

Do not drive or use machines if you experience any side effect which may lessen your ability to do so such as nausea, vomiting, worsening of eyesight, or changes to your vision and hearing.

The Carboplatin Intravenous Infusion vial stopper contains dry natural rubber

The vial stopper contains dry natural rubber (a derivative of latex), which may cause allergic reactions.

3. How to use Carboplatin Intravenous Infusion This medicine will be given by infusion (drip) into a vein over 15-60 minutes.

Dose

Your doctor will work out the correct dose of carboplatin for you and how often it must be given. The recommended dose will depend on your medical condition, your size and how well your kidneys are working. Your doctor will tell how well your kidneys are working using blood or urine samples.

You will have regular blood tests after your dose of carboplatin. You may also have checks for nerve damage and hearing loss.

There is likely to be about 4 weeks between each dose of carboplatin.

If you are given too much Carboplatin Intravenous Infusion than you should

This medicine will be given to you in a hospital, under the supervision of a doctor. It is unlikely that you will be given too much or too little, however, tell your doctor or nurse if you have any concerns.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, tell your doctor immediately:

- abnormal bruising, bleeding, or signs of infection such as a sore throat and high temperature
- severe allergic reaction (anaphylaxis/anaphylactic reactions) - you may experience a sudden itchy rash (hives), swelling of the hands, feet, ankles, face, lips, mouth or throat (which may cause difficulty in swallowing or breathing), and you may feel you are going to faint
- haemolytic-uraemic syndrome (a disease characterised by acute kidney failure), decreased

urination or blood in the urine

These are serious side effects. You may need urgent medical attention.

Very common: may affect more than 1 in 10 people

- tiredness, shortness of breath and paleness caused by anaemia (a condition in which there is a decreased number of red blood cells)
- feeling sick (nausea) or being sick (vomiting)
- stomach pain and cramp

Tests may also show:

- changes in your red and white blood cells and platelets (myelosuppression)
- increase in the level of urea in your blood
- decrease in the level of sodium, potassium, calcium and magnesium in your blood
- decrease in renal creatinine clearance
- abnormal liver enzyme levels

Common: may affect up to 1 in 10 people

- signs of infection such as fever or sore throat
- flu-like symptoms
- symptoms of severe allergic reaction include sudden wheeziness or tightness of chest, swelling of the eyelids, face or lips, facial flushing, low blood pressure, rapid heart beat, hives, shortness of breath, dizziness and anaphylactic shock
- tingling or numbness in your hands, feet, arms or legs
- burning or prickling sensation
- decreased tendon reflex
- taste disturbance or loss of taste
- temporary worsening of eyesight or changes to your vision
- ringing in the ears or changes in your hearing
- heart disorders
- tightness of the chest or wheezing
- interstitial lung disease (a group of lung disorders in which the deep lung tissues become inflamed)
- diarrhoea or constipation
- sore lips or mouth ulcers (mucous membrane disorders)
- hair loss
- rash and/or itchy skin
- pain or discomfort in your bones, joints, muscles, or surrounding structures (musculoskeletal disorder)
- problems with your kidneys or urine
- extreme tiredness/weakness (asthenia)

Tests may also show:

- increased level of bilirubin and creatinine in your blood
- increased level of uric acid in your blood which may lead to gout

Rare: may affect up to 1 in 1,000 people

- temporary sight loss

Very rare: may affect up to 1 in 10,000 people

- scarring of the lungs which causes shortness of breath and/or cough (pulmonary fibrosis)

Not known: frequency cannot be estimated from available data

- cancers caused by treatment with carboplatin (secondary malignancies)
- feeling unwell with high temperature due to low levels of white blood cells (febrile neutropenia)
- a group of symptoms such as headache, altered mental functioning, seizures and abnormal vision (from blurriness to vision loss). These are symptoms of reversible posterior leukoencephalopathy syndrome, a rare neurological disorder
- dry mouth, tiredness, and headache due to excessive loss of body water (dehydration)
- loss of appetite, anorexia
- pancreatitis
- stroke (sudden numbness or weakness in the face, arm, or leg, especially on one side of the body)
- severely impaired liver function, damage or death of liver cells
- heart failure
- obstruction in blood vessel (embolism), swelling or tenderness of leg/arm
- changes in blood pressure (hypertension or hypotension)
- skin disorders such as hives, rash, skin redness (erythema), and itching
- swelling or soreness where the injection was given
- lung infection

Carboplatin may lead to problems with your blood, liver and kidneys. Your doctor will take blood samples to check for these problems.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Carboplatin Intravenous Infusion

Keep this medicine out of the sight and reach of children.

Expiry

Do not use this medicine after the expiry date which is stated on the vial label and carton after 'EXP'. Where only a month and year is stated, the expiry date refers to the last day of that month.

Storage

This medicine comes in two types of vial, CARBOPLATIN VIAL- TAJ PHARMA and standard vials.

CARBOPLATIN VIAL- TAJ PHARMA - store in a refrigerator (2 to 8°C). Keep the vial in the outer carton in order to protect from light.

Standard vials – Do not store above 25°C. Keep the vial in the outer carton in order to protect from light. If Carboplatin for Intravenous Infusion is diluted

before use, the diluted solution should be used immediately. If not used immediately it should not normally be stored for longer than 24 hours at 2 to 8°C.

6. Contents of the pack and other information

What Carboplatin Intravenous Infusion contains

The active substance is carboplatin. Each millilitre (ml) of solution contains 10 milligrams (mg) of carboplatin.

The other ingredient is water for injections. Also see section 2 The Carboplatin Intravenous Infusion vial stopper contains dry natural rubber.

What Carboplatin Intravenous Infusion looks like and contents of the pack

Carboplatin Intravenous Infusion is a clear, colourless solution for infusion which comes in glass containers called vials.

It may be supplied in packs containing:

- 1 x 50 mg/5 ml vial or CARBOPLATIN VIAL- TAJ PHARMA
- 1 x 150 mg/15 ml vial or CARBOPLATIN VIAL- TAJ PHARMA
- 1 x 450 mg/45 ml vial or CARBOPLATIN VIAL- TAJ PHARMA
- 1 x 600 mg/60 ml vial or CARBOPLATIN VIAL- TAJ PHARMA

Not all packs may be marketed.

Marketing authorisation holder and manufacturer

Manufactured in India by: TAJ PHARMACEUTICALS LTD. TAJ GROUP Mumbai, India at SURVEY NO.188/1 TO 189/1,190/1 TO 4, ATHIYAWAD, DABHEL, DAMAN- 396210 (INDIA)

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Carboplatin 10 mg/ml Intravenous Infusion carboplatin

The following information is intended for medical or healthcare professionals only

Further to the information included in section 3, practical information on the preparation/handling of the medicinal product is provided here.

Parenteral drugs should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If particulate matter is observed, shake and re-inspect. Vials with visible particulate matter should not be used.

Incompatibilities

Carboplatin may interact with aluminium to form a black precipitate. Needles, syringes, catheters or IV administration sets that contain aluminium parts which may come into contact with carboplatin,

should not be used for the preparation or administration of the drug.

Handling

Carboplatin should be prepared for administration only by professionals who have been trained in the safe use of chemotherapeutic agents.

Carboplatin solution for infusion may be further diluted in Glucose 5% and administered as an intravenous infusion. Chemical and physical in-use stability has been demonstrated for 56 days to final concentrations of 0.2 mg/ml and 3.5 mg/ml when stored at 2 to 8°C in non-PVC (polyolefin) infusion bags when protected from light.

Carboplatin solution for infusion may also be further diluted in Sodium Chloride 0.9% and administered as an intravenous infusion. The infusion solution is chemically stable for up to 24 hours when stored at 2 to 8°C and up to 8 hours when stored at 22°C. From a microbiological point of view however, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

Contamination

In the event of contact of carboplatin with eyes or skin, wash affected area with copious amounts of water or normal saline. A bland cream may be used to treat transient stinging of skin. Medical advice should be sought if the eyes are affected.

In the event of a spillage, two operators should put on gloves and mop up the spilled material with a sponge kept for that purpose. In the event of a powder spillage, cover with a cloth and moisten with water before mopping up.

Rinse the area twice with water. Put all solutions and sponges in a plastic bag, seal and label with the words 'CYTOTOXIC WASTE' and incinerate.

Disposal

Syringes and Carboplatin-VIALS, containers, absorbent materials, solutions and other material which have come into contact with carboplatin should be placed in a thick plastic bag or other impervious container and incinerated at 1000°C.

Directions for use of the CARBOPLATIN VIAL- TAJ PHARMA Carboplatin-VIALS should be used with the appropriate Hospira administration device. The vial stopper contains dry natural rubber (a derivative of latex), which may cause allergic reactions.

